

ALL ABOUT CLEANROOMS

1. INTRODUCTION TO CLEANROOMS -HISTORY, CONCEPTS AND STANDARDS

What is a cleanroom?

Cleanroom is a specially created controlled environment, to aid certain engineering processes. Widely used in manufacturing and research of semiconductors, electronics, aerospace components, pharmaceutical and biotech processes, cleanrooms have low level of airborne pollutants, microbes, vapors etc. to aid certain engineering processes.

As per ISO 14644-1:2015,

“A cleanroom is a room in which the concentration of airborne particles is **CONTROLLED**, and which is **CONSTRUCTED** and used in a manner to minimise the **INTRODUCTION**, **GENERATION**, and **RETENTION** of particles inside the room and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary.

Cleanrooms are

- maintained at higher pressure compared to adjacent areas to minimise **INTRODUCTION** of airborne particles.
- built with materials that do not generate particles and the the personnel wear cleanroom clothing that controls dispersion, thereby minimising the **GENERATION** of particles.
- supplied with large quantities of highly filtered air that removes airborne particles instantly, either by dilution effect or piston effect. This is how **RETENTION** of particles is tackled.

Why are cleanrooms required?

Cleanrooms are required

- Airborne particles or contaminants affect the quality of products.
- Cleanroom personnel, machinery, building structure, adjacent areas produce particles or contaminants.
- Cleanrooms continuously filter these particles out to maintain cleanliness in the production zone.

Sources of contaminants

- Facilities
 - Walls, floors, and ceilings
 - Paint and coatings
 - Construction materials
 - Debris
 - air and vapours
 - Spills and leaks
- Personnel
 - Skin flakes, oil, and particles
 - Cosmetics and perfumes
 - Clothing debris
 - Hair & Water vapor
- Other particles of sneezing and breathing
- Tools
 - Non cleanroom materials
 - wear and tear particles
 - Machinery vibration
 - Lubricants and emissions
 - Brooms, mops, and dusters
 - Raw-material bags and containers
- Fluids
 - Particulates floating in air
- Bacteria, organics, and moisture
- Floor finishes or coatings
- Cleaning chemicals
- Plasticizers (off-gasses)
- Deionized water
- Products
 - Silicon chips
 - Quartz flakes
 - Clean room debris
 - Metal particles

Human Activity

Humans contribute to more than two-third of contamination generation in the cleanrooms

Activity	Particles / min (0.3 µm & larger)
Motionless	100,000
Walking (3 km/h)	5,000,0000

Activity	Particles / min (0.3 µm & larger)
Walking (8 km/h)	10,000,000
Running	100,000,0000

Usage Industries

Cleanrooms are used in many industries such as

- Pharmaceuticals
- Biotechnology
- Laboratories
- Hospitals
- Electronics
- Semiconductors
- Automotive
- Aerospace
- Medical devices
- Food & beverages
- R&D Facilities
- Electronic components
- Optical products
- Sterile products
- Integrated circuits

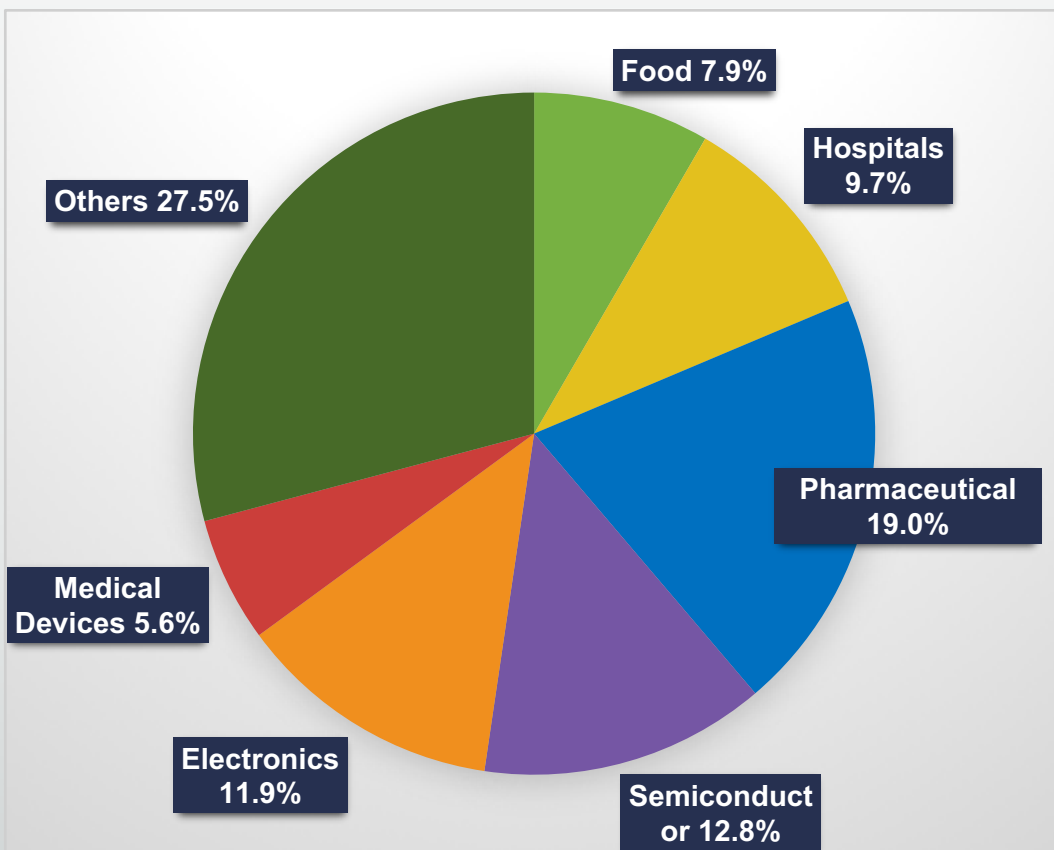


Fig 1- Estimated Cleanroom Area Usage by Industries

Pharmaceutical, biotech, hospitals, semiconductors, electronic manufacturing facilities are the largest users of cleanrooms.

Cleanroom industry is very fast growing as many of the companies are moving towards cleaner and stringent manufacturing process to provide with better quality products.

History of Cleanrooms

Hospitals were the first users of cleanrooms. The usage dates back to 19th century. Lord Lister at Royal Infirmary, Glasgow, in 1860, used Carbolic Acid to kill bacteria, clean the surgical instruments, wound and surgeons hands to contain infections.



Physicians at Aberdeen Royal Infirmary in Scotland using Lister's spray in 1889.

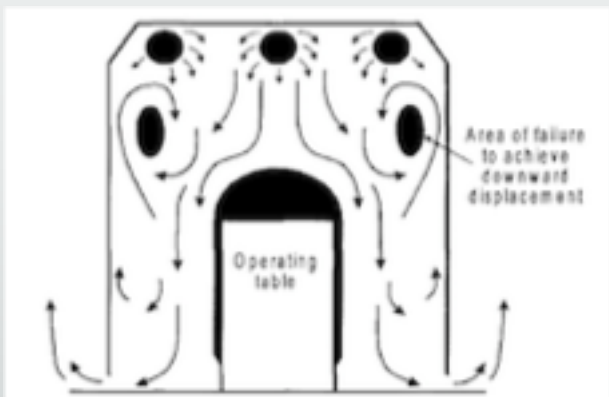


An hospital operating room in 1890. You may notice doctors wearing gowns to minimise contamination.



Operating room in 1907 with the clinicians wearing masks, gowns, gloves.

It is only after the World War-II that the other industries cleanroom technology. Other industries such as optics, gyroscopes, pharma, aerospace and defence components embraced cleanrooms to aid qualitative manufacturing.



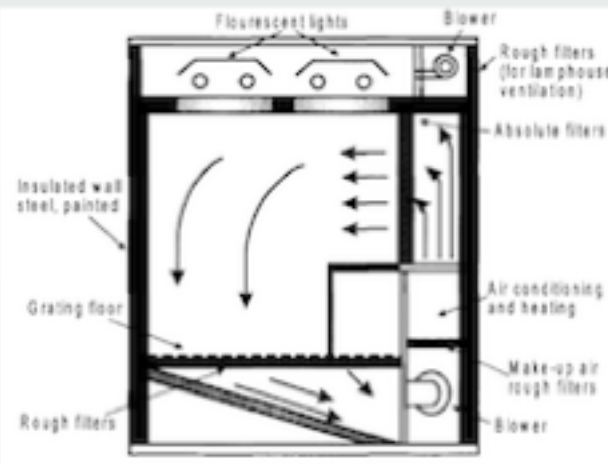
Downward "Piston-Effect" Cleanroom at Washington Hospital, Manchester, developed by Sir John Charnley, pioneer of hip replacement surgery led to the evolution of unidirectional (laminar) flow cleanrooms.



Western Electric producing gyroscopes, 1955, in a cleanroom with vinyl flooring & HEPA Filters



Mr. Whitefield in the cleanroom he invented.



Cross-section of the original unidirectional airflow room.

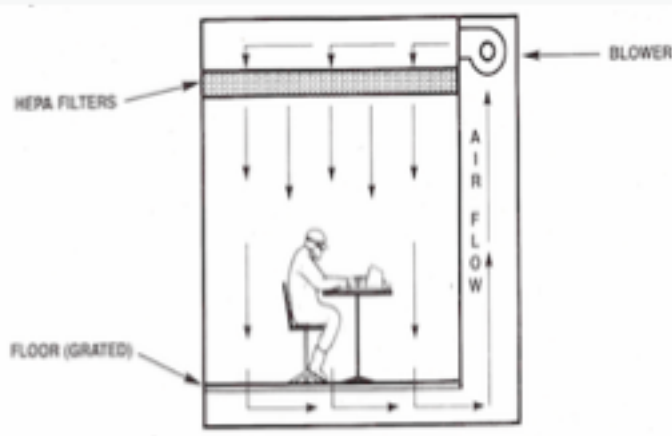
Invention of unidirectional or laminar flow cleanrooms

- Invention of Laminar flow or unidirectional flow cleanrooms was a revolution in the entire manufacturing industry. The credit goes to Texas born Physicist Willis J Whitefield and his team. He is also regarded as the father of modern cleanrooms.
- The team working at Sandia Laboratories, Albuquerque, New Mexico, USA, constructed a Laminar Flow cleanroom of small size of 1.8 m W x 3 m L x 2.1 m H, in the year 1961.
- The supply air was supplied through a bank of High Efficiency Particulate Air (HEPA) filters
- The return air was sucked out through a grating floor, through which the contaminants generated swept away
- The concept of unidirectional flow cleanroom ventilation was very quickly adopted by a large variety of industries, as high quality cleanrooms were urgently required.
- HEPA filters (also called Absolute Filters then) removed 99.95% of 0.3 micron particles
- The room was positively pressurised to eliminate the chances of contaminants from the adjacent rooms.

Types of Cleanrooms

The cleanrooms are classified based on the method employed for ventilating the room. There are three types of cleanrooms, **Unidirectional, Non-Unidirectional & Mixed Airflow Cleanrooms**

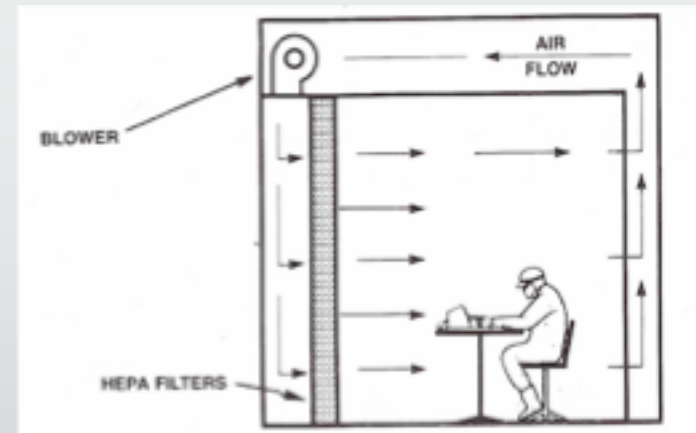
1. Unidirectional Cleanrooms



Vertical unidirectional (laminar) airflow clean room.

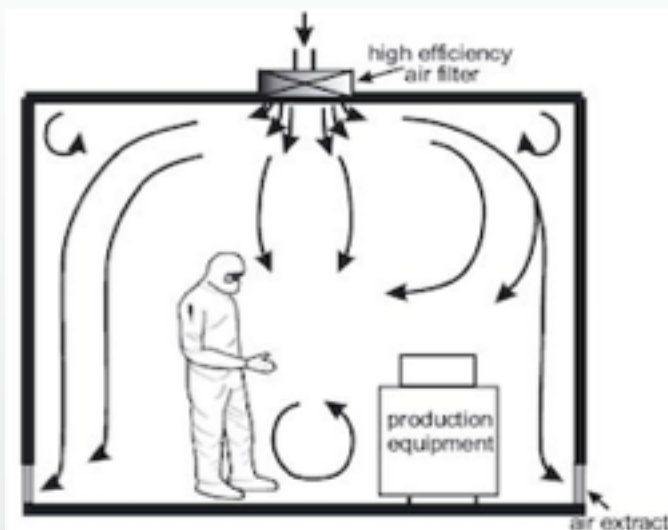
- Unidirectional are also called as **Laminar Airflow** Cleanrooms.
- These cleanrooms use **more** air volume and provide superior cleanliness
- HEPA or ULPA filters are installed in the ceiling or wall that allow the air to pass through the **cross-section** of the room, either vertically or horizontally.
- In a vertical down flow, the entire room is bathed in a **uniform shower** of downward-flowing ultra clean air. The contamination generated in the space is swept down and out through the floor. (Piston Effect)
- The air flows linearly at a velocity of **0.4-0.5 M/Sec (~90 Ft/min)**
- Return air is **extracted** either through the grated / raised floor or through return air risers located close to the floor.

- ISO Class 5 or cleaner areas have unidirectional flow, with air changes per hour (ACPH) of at least **240**.
- In a horizontal flow, air enters from one wall and returns on the opposite.
- The ceiling shall be complete with HEPA/ULPA Filters (70-100%)
- Horizontal UD cleanrooms have some **limitations** such as any obstruction in the room blocks the complete flow, the air becomes contaminated after leaving the first work station leaving dirty air to workstations behind, movement of personnel also degrades the flow.
- Unidirectional flow cleanrooms find **application** in semiconductors, aerospace components, precision electronics etc.



Horizontal unidirectional (laminar) airflow clean room.

2. Non-unidirectional Cleanrooms

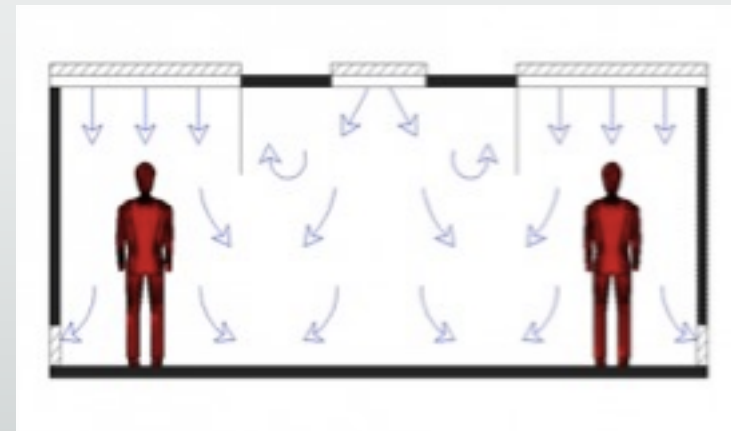


Non-unidirectional airflow clean room.

- Non-Unidirectional are also called as **Turbulently Ventilated** Cleanrooms.
- These cleanrooms use **less** air volume compared to laminar flow.
- The clean air shall be pumped into the room through ceiling mounted or plenum mounted HEPA filters, that dilute the contaminated air, thereby by improving the cleanliness by reducing the particle count.
- The return air shall be extracted through return air risers at the bottom or ceiling mounted grills/ diffusers.
- ISO Class 6 or less cleaner areas have non-unidirectional flow, with air changes per hour (ACPH) in the range of **20-120**.
- These cleanrooms find application in pharmaceuticals, biotechnology, R&D Labs, food & beverages etc.

3. Mixed Flow Cleanrooms

- Mixed flow cleanrooms have a combination of Unidirectional & Non-unidirectional flow patterns, based on the special requirements.
- Most of the cleanroom shall be non-unidirectional with localised laminar airflow stations.
- For e.g. in a pharma dispensing booth, entire room shall be a non-unidirectional cleanroom (ISO Class 7 or 8), but the dispensing booth shall be ISO Class 5. in these cases, it is not viable to make the entire room ISO-5 classified.
- These cleanrooms find application in pharmaceuticals, biotechnology, R&D Labs etc.



Mixed airflow clean room.

Brief history of cleanroom classification

- Technical Order (T.O.) 00-25-203 by U.S. Airforce, in 1961 is the first of cleanroom standards.
- It covered cleanroom design concepts, permissible particle count and operating procedures such as entry, exit, clothing, men and material movement etc.
- However, Federal Standard 209 is considered to be the most widely accepted and used cleanroom standard across the world for decades. This was a benchmark for decades.
- The particle concentration was supposed to be measured at equal to and greater than $0.5\ \mu\text{m}$, as this was the range of sizes that was easily measurable by particle counters.
- At the end of 20th century, ISO-14644 standard superseded all other cleanroom standards existed till then.
- ISO 14644 and Fed 209 also served as a reference to industry-specific standards such as GMPs in pharma.
- Many countries have come up with their own cleanroom standards.
- Cleanrooms are mainly classified according to number and size of particles permitted per unit volume of air (Particles / cubic meter or particles/ cubic feet).
- $0.1\ \mu\text{m}$, $0.2\ \mu\text{m}$, $0.3\ \mu\text{m}$, $0.5\ \mu\text{m}$, $1.0\ \mu\text{m}$ and $5.0\ \mu\text{m}$ are the commonly used particles sizes for defining the airborne particle concentration limits.

Cleanroom Classification Standards

Timeline Of Cleanroom Standards



1960	1970	1980	1990	2000-10
U.S. Air Force TO 00-25-203	Fed 209 B	Fed 209 C	Fed 209 E	ISO 14644-2 To ISO 14644-14
US-MIL-STD-1246	Germany VDI 2083:3	Fed 209 D	ISO 14644-1	
Fed 209	Australia AS 1386		RUSSIA GOST R 50766	
Fed 209A	Britain BS 5295			
	Japan JIS B 9920			
	France AFNOR X44101			

Comparison of international cleanroom standards

ISO 14644	FED 209 D (1988)	FED 209 E (1992)	BS 5295 (1989)	AS 1386 (1989)	AFNOR X44101(1989)	VDI 2083 (1990)	JIS B 9920 (1990)	EU GMP (2010)
Class-1	-	-	-	-	-	-	1	-
Class-2	-	-	-	-	-	0	2	-
Class-3	1	M 1.5	C	0.035	-	1	3	-
Class-4	10	M 2.5	D	0.35	-	2	4	-
Class-5	100	M 3.5	E / F	3.5	4000	3	5	A / B
Class-6	1 000	M 4.5	G / H	35	-	4	6	-
Class-7	10 000	M 5.5	J	350	400 000	5	7	C
Class-8	100 000	M 6.5	K	3500	4 000 000	6	-	D
Class-9	-	-	-	-	-	-	-	-

Cleanroom Classification Standards

History of Federal 209 Standard

1963	1966	1976	1987	1988	1992
Fed 209	Fed 209 A	Fed 209 B	Fed 209 C	Fed 209 D	Fed 209 E

*Federal Standard 209 was cancelled in 2001

Airborne Particulate Cleanliness Classes As Per FED 209E

Class Name		Class Limits (particles per ft3) with sizes equal to and larger than the particle sizes				
SI	English	0.1 µm	0.2 µm	0.3 µm	0.5 µm	5.0 µm
M 1		9.91	2.14	0.875	0.283	-
M 1.5	1	35	7.5	3	1	-
M 2		99.1	21.4	8.75	2.83	-
M 2.5	10	350	75	30	10	-
M 3		991	214	87.5	28.3	-
M 3.5	100	-	750	300	100	-
M 4		-	2,140	875	283	-
M 4.5	1 000	-	-	-	1,000	7
M 5		-	-	-	2,830	17.5
M 5.5	10 000	-	-	-	10,000	70
M 6		-	-	-	28,300	175
M 6.5	100 000	-	-	-	1,00,000	700
M 7		-	-	-	2,83,000	1,750

Cleanroom Classification Standards

International Standard ISO 14644

- ISO 14644 and parts are the most widely used cleanroom standards across the world. Federal standard is also still used alongside ISO 14644 in some parts of the world and still acceptable to use Fed 209E.
- ISO 14644 (Cleanrooms and associated controlled environments) and its parts from 1 through 16 cover all aspects of cleanrooms right from air cleanliness classifications, testing, construction and designing of cleanrooms, cleanroom operations, separative devices, energy efficiency, nanoscale and chemical particle concentration etc.

Parts of ISO 14644 Standard

Part	Description
ISO 14644-1	Classification of air cleanliness
ISO 14644-2	Specifications for testing and monitoring
ISO 14644-3	Test Methods
ISO 14644-4	Design, construction and start-up
ISO 14644-5	Operations
ISO 14644-6	Vocabulary
ISO 14644-7	Separative devices (clean air hoods, gloveboxes, isolators and minienvironments)
ISO 14644-8	Classification of airborne molecular contamination
ISO 14644-9	Classification of surface cleanliness by particle concentration
ISO 14644-10	Classification of surface cleanliness by chemical concentration

Part	Description
ISO 14644-11	-
ISO 14644-12	Specifications for monitoring air cleanliness by nanoscale particle concentration
ISO 14644-13	Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications
ISO 14644-14	Assessment of suitability for use of equipment by airborne particle concentration
ISO 14644-15	Assessment of suitability for use of equipment and materials by airborne chemical concentration
ISO 14644-16	Energy efficiency in cleanrooms and separative devices
ISO 14644-17	Particle deposition rate applications (under development as on 1 st Apr, 2019)

- International Standard ISO 14644-1:2015(E), Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration, ©ISO 2015.
- Cleanroom Technology: Fundamentals of Design, Testing and Operation by W. Whyte © 2001, published by John Wiley & Sons Ltd.
- ASHRAE Design Guide for Cleanrooms: Fundamentals, Systems, and Performance, © 2017

For more articles on Cleanrooms and HVAC, please visit the link below

<https://www.unikelvin.com/downloads>



- Cleanroom
- Commercial HVAC
- Modular Panels
- Interiors & Flooring
- Chilled Water Systems
- Electrical Systems
- Integrated BMS
- Laboratory Furniture
- Cleanroom Equipment
- HVAC Maintenance Services

#60/A, 2nd Floor, Next to Karnataka Bank,
Bommasandra Main Road, Bommasandra Industrial
Area, Bangalore. PIN- 560099, Ph: +91-80-4377 8866
E-Mail: info@unikelvin.com, Web: www.unikelvin.com